Department of Defense Healthcare Provider's Briefing

SMALLPOX

9 Oct 08

Purpose

To provide healthcare providers with an introduction to smallpox disease and vaccination procedures

Key Messages

- Preserving the health and safety of our people is our top concern
- Smallpox vaccine prevents smallpox, but requires very careful use
- Smallpox would disrupt military missions, because it is contagious and deadly
- Smallpox protection helps our War on Terrorism; new threats require new measures of force protection

Policies

Smallpox Vaccination:

- Mandatory for personnel assigned to CENTCOM AOR, the Korean Peninsula and USPACOM Forward Deployed Naval Forces for 15+
- Required for Smallpox Response Teams
- Can be given up to 120 days before deployment
- Policy requires ACAM2000 Medication Guide and DoD smallpox trifold distribution
- Recipients must be screened
  - Screening form located at www.smallpox.mil/screeningform

Smallpox in History

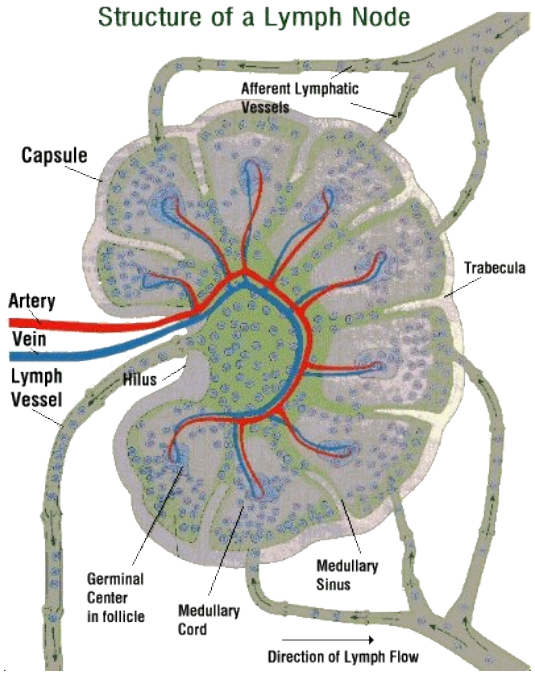
- 1776: Smallpox – U.S. forces too weak to capture Quebec
  - 5,500 smallpox casualties out of 10,000 forces
  - George Washington orders variolation of Continental Army against smallpox (archaic procedure, 2% fatal)
- 1796: Europe (w/o Russia)—smallpox kills 400,000 people, causes 1/3 of blindness
- 1796: Edward Jenner uses cowpox virus from milkmaid to prevent smallpox in young boy
- 1812: War Department orders Jennerian vaccination of U.S. troops
- 1890s: National Anti-Vaccination League, political riots in UK
- 1919: Citizens outraged that Woodrow Wilson permits smallpox vaccination of Armed Forces
- 1980: WHO declares Earth free of smallpox
- 1984: DoD restricts vaccination to recruits at basic training
- 2002: DoD resumes Smallpox Vaccination Program
- 2007: FDA approves ACAM2000
- 2008: DoD begins using new vaccine, ACAM2000

Epidemiology of Smallpox

- Smallpox was once worldwide in scope and was declared eradicated from the Earth in 1980
- Smallpox spreads primarily by prolonged (> 1 h) face-to-face contact (< 6.5 feet)
- A smallpox patient is most infectious from onset of rash, marked by temperature > 101°F (38.8°C)
- A smallpox case, on average infects 3 to 5 other people
- 15 days between generations of smallpox cases
- As scabs form, infectivity decreases rapidly

Pathogenesis

- Infectious dose unknown, but believed to be only a few virions
- Natural infection occurs after virus implants on oropharyngeal, respiratory mucosa
- Virus migrates and multiplies in regional lymph nodes
- Symptomatic viremia develops on day 3 or 4
- Secondary viremia begins on 8th day, followed by fever & toxemia
- Virus localizes in small blood vessels of skin and infects adjacent cells



Smallpox Infection Timeline

Post-exposure vaccination fully or partially protective through day 3 after exposure.

Average smallpox case infects 3 to 5 people. About half of close contacts are infected.

First symptoms develop 7 to 17 days after exposure; average depicted here as day 11.

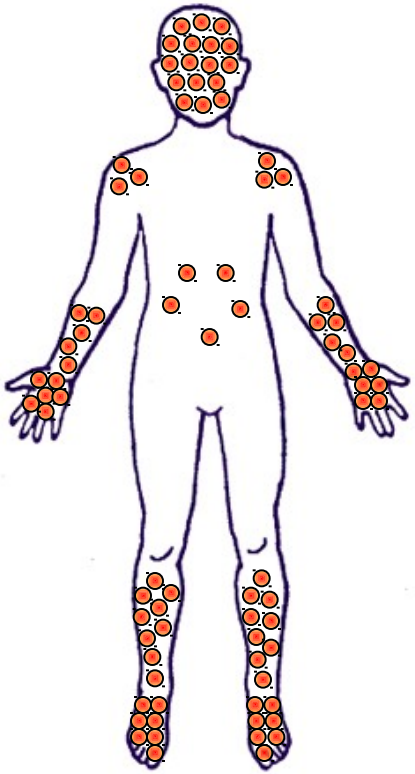
After symptoms develop, isolate case. Trace and vaccinate contacts.

Communicability	Exposure = Day 0	Symptoms	Day of Symptoms	Disease Progress
Not contagious	Day 1	No symptoms		Virus introduced to respiratory tract
	2			
	3			Virus appears in lymph nodes
	4			
	5			
	6			Virus replicates in lymph system
	7			
	8			
	9			
	10			
	11	First symptoms	Day 1	
	12		2	Fever, backache, headache, nausea, malaise
Contagious	13		3	
	14		4	
	15	Rash	5	Macules (spots)
Very contagious	16		6	Papules (bumps, pimples)
	17		7	
	18		8	
	19		9	Vesicles (blisters)
	20		10	
Contagious	21		11	Pustules (pus-filled blisters)
	22		12	
	23		13	
	24		14	
	25		15	Scabs
Scabs contagious	26		16	
	27		17	
	28		18	
	29		19	
	30		20	
Not contagious	31		Scars	
	32			

Smallpox Development

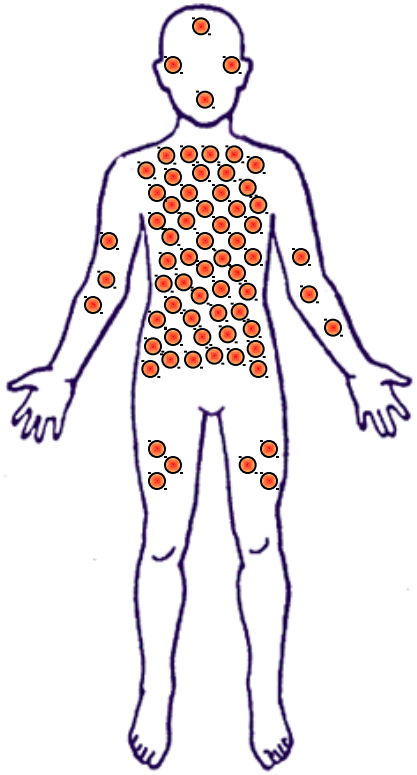
Differential Diagnosis

Smallpox (Variola)



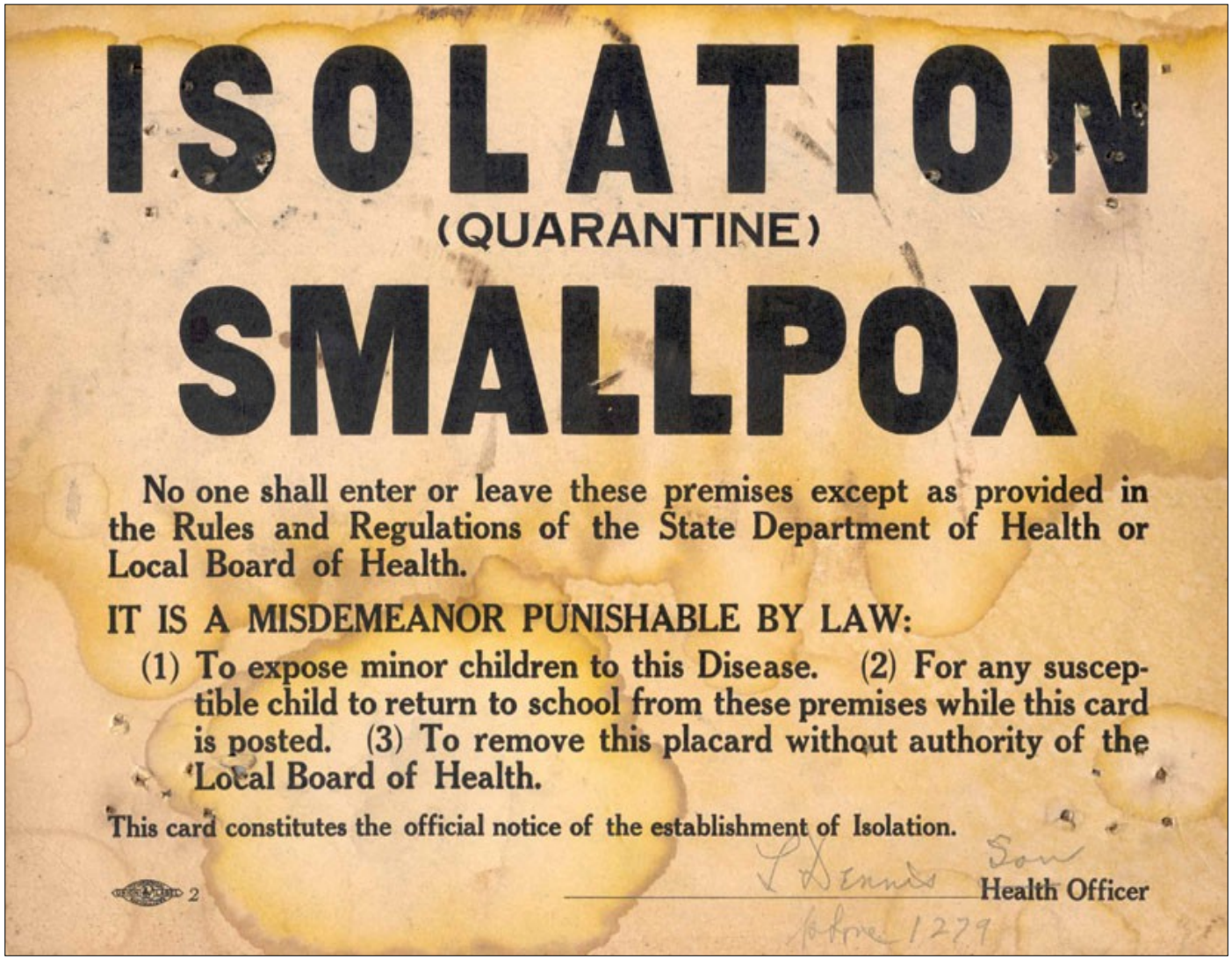
- Lesions appear in 1 to 2 day period
- On any part of body, lesions in same stage of development
- Lesions most dense on face and extremities

Chickenpox (Va



- New lesions appear in crops every few days
- Lesions at different stages of maturation
- More lesions on trunk than face and extremities

Historical Quarantine Plaque



ISOLATION

(QUARANTINE)

SMALLPOX

No one shall enter or leave these premises except as provided in the Rules and Regulations of the State Department of Health or Local Board of Health.

IT IS A MISDEMEANOR PUNISHABLE BY LAW:

(1) To expose minor children to this Disease. (2) For any susceptible child to return to school from these premises while this card is posted. (3) To remove this placard without authority of the Local Board of Health.

This card constitutes the official notice of the establishment of Isolation.

2

Health Officer

Care of Smallpox Patient

- Supportive therapy helps reduce fever, pain, etc., but no established treatment for smallpox
- Smallpox vaccination up to 3 days after someone is exposed to smallpox virus will prevent or reduce the severity of smallpox in most people
- Vaccination 4 to 7 days after exposure likely offers partial protection
- Pre-exposure vaccination protects 95% of people from getting smallpox.
- Cidofovir used to treat smallpox under IND protocols, but no human efficacy data

Smallpox would disrupt military missions because it is contagious and deadly

- Before smallpox was eradicated, it killed many millions of people over hundreds of years
- Terrorists or governments hostile to US may have or could obtain variola virus
- A smallpox outbreak would significantly affect military readiness
- An outbreak could restrict movement of troops, aircraft, ships
- S ress r to r
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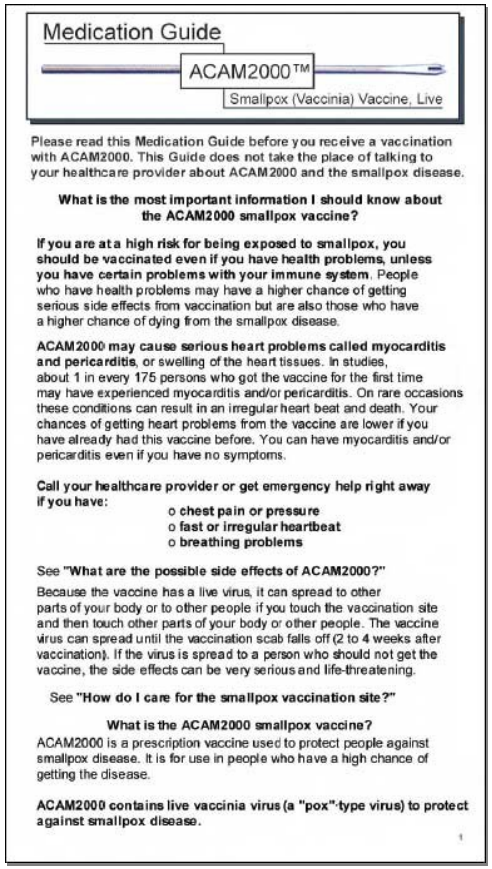
Smallpox Vaccine

- The current vaccine in use in the United States is a new cell culture vaccine that is a derivative of the Dryvax vaccine that was used during the global smallpox eradication program
- Dryvax was made from a virus called *vaccinia*, which is another “pox”-type virus related to smallpox
- ACAM2000, is manufactured by Acambis
- Live Vaccinia virus (NYCBOH strain) not smallpox (variola) virus
- Percutaneous inoculation with bifurcated needle (scarification)
  - Pustular lesion/induration surrounding central scab/ulcer 6-8 days post-vaccination
  - Vaccine protects within a few days of vaccination
  - A cutaneous response demonstrates successful vaccination
  - Immunity not lifelong

Comparison Chart



Medication Guide

ACAM2000™

Smallpox (Vaccinia) Vaccine, Live

Please read this Medication Guide before you receive a vaccination with ACAM2000. This Guide does not take the place of talking to your healthcare provider about ACAM2000 and the smallpox disease.

What is the most important information I should know about the ACAM2000 smallpox vaccine?

If you are at a high risk for being exposed to smallpox, you should be vaccinated even if you have health problems, unless you have certain problems with your immune system. People who have health problems may have a higher chance of getting serious side effects from vaccination but are also those who have a higher chance of dying from the smallpox disease.

ACAM2000 may cause serious heart problems called myocarditis and pericarditis, or swelling of the heart tissues. In studies, about 1 in every 175 persons who got the vaccine for the first time may have experienced myocarditis and/or pericarditis. On rare occasions these conditions can result in an irregular heart beat and death. Your chances of getting heart problems from the vaccine are lower if you have already had this vaccine before. You can have myocarditis and/or pericarditis even if you have no symptoms.

Call your healthcare provider or get emergency help right away if you have:

- o **chest pain or pressure**
- o **fast or irregular heartbeat**
- o **breathing problems**

See **"What are the possible side effects of ACAM2000?"**

Because the vaccine has a live virus, it can spread to other parts of your body or to other people if you touch the vaccination site and then touch other parts of your body or other people. The vaccine virus can spread until the vaccination scab falls off (2 to 4 weeks after vaccination). If the virus is spread to a person who should not get the vaccine, the side effects can be very serious and life-threatening.

See **"How do I care for the smallpox vaccination site?"**

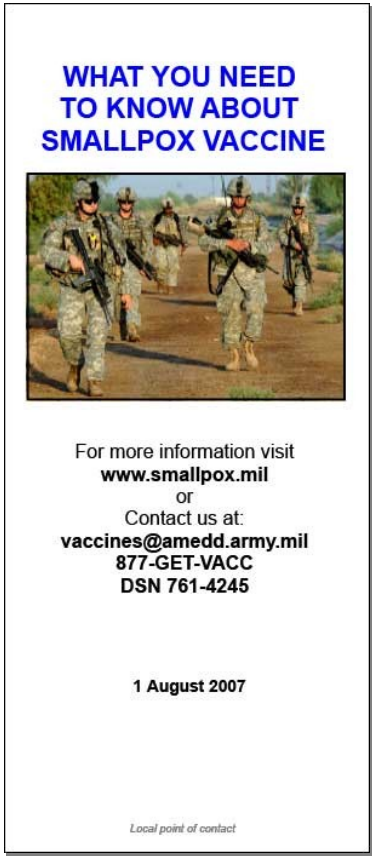
What is the ACAM2000 smallpox vaccine?

ACAM2000 is a prescription vaccine used to protect people against smallpox disease. It is for use in people who have a high chance of getting the disease.

ACAM2000 contains live vaccinia virus (a "pox"-type virus) to protect against smallpox disease.

1

	ACAM2000™
Manufacturer	Acambis Inc.
Indication	For the induction of immunity against Smallpox
Description	Live vaccinia virus manufactured using cell culture technology
Pharmaceutical Properties	~ 2% human serum albumin USP, 0.5-0.7% sodium chloride USP, 5% mannitol USP, and trace amounts of neomycin and polymyxin B ~ Diluent for ACAM2000 contains 50% (v/v) Glycerin USP, 0.25% (v/v) Phenol USP in Water for Injection USP supplied in 3mL clear glass vials containing 0.6mL of diluent ~ 100 dose vial
Medium	Vero (African Green Monkey kidney cells)
Route	Percutaneous using a bifurcated needle traditionally at an upper deltoid site (Also called scarification)
Dosing	Primary: 15 Jabs Revaccination:15 Jabs
Revaccination	DoD policy requires individuals at high risk for exposure, such as laboratory personnel handling variola virus, be re-vaccinated every 3 years. Individuals deemed to be at an increased risk, such as segments of the military must be re-vaccinated every 10 years.
Storage & Handling	~ Un-reconstituted ACAM2000 vaccine is shipped and stored at 2-8°C (36-46°F) ~ Un-reconstituted ACAM2000 vaccine should not be exposed to room temperature (23-27°C, 73-81°F) for more than 48 hours ~ After reconstitution, ACAM 2000 vaccine may be administered within 6 to 8 hours at room temperature (20-25°C, 68-77°F) ~ Vaccine must be discarded as a bio-hazardous material 30 days after reconstitution ~ Gloves should be worn when reconstituting or administering ACAM2000 vaccine ~ Expiration dates will not be extended
Required Educational Material	DoD Smallpox individual information trifold brochure AND *Medication Guide*



WHAT YOU NEED TO KNOW ABOUT SMALLPOX VACCINE

For more information visit
www.smallpox.mil
or
Contact us at:
vaccines@amedd.army.mil
877-GET-VACC
DSN 761-4245

1 August 2007

Local point of contact

www.smallpox.mil/ACAM2000

Smallpox Vaccine Effectiveness

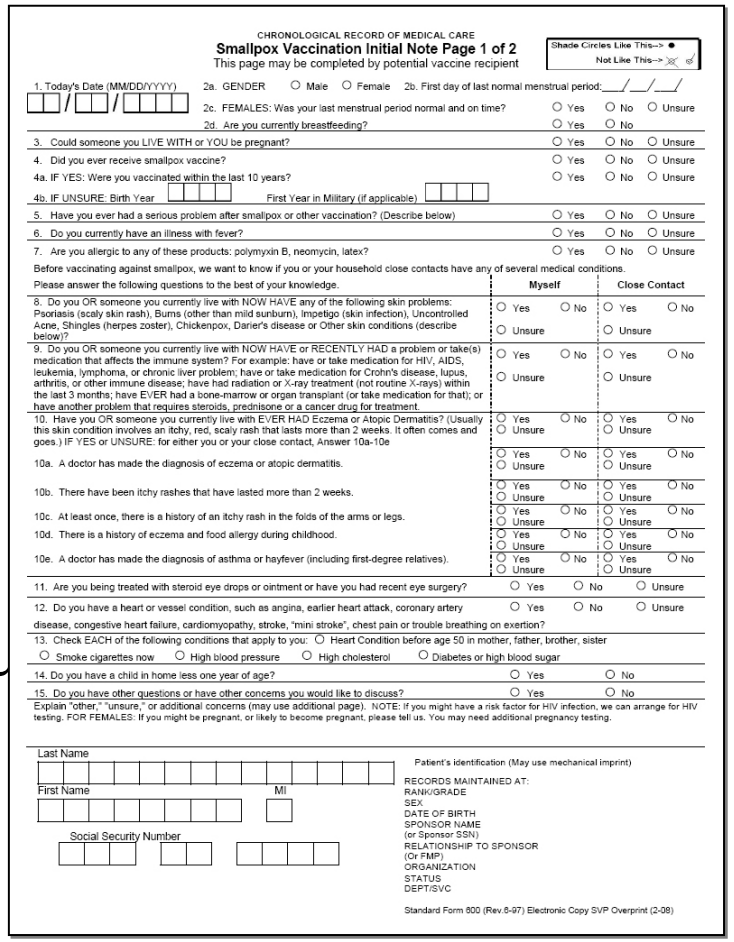
Smallpox vaccine prevents smallpox but requires very careful use

- World Health Organization (WHO) used Dryvax vaccine to eradicate natural smallpox
  - 95% of people are protected within 10 days (some may take longer)
  - Solid protection lasts for 3 years; partial protection lasts longer
  - ACIP recommends people at high risk for exposure be revaccinated every 10 years (pre-event); during an actual event, consider revaccinating if more than 3 years has elapsed since last vaccination
  - Can protect up to 3 days after exposure
- Contains live vaccinia virus, cannot cause smallpox

Screening

- Carefully read & complete screening form; medical professionals available to explain in layman's terms
- Ask for clarification if unsure how to answer screening questions
- Contact family members who may know about childhood history of recurrent rashes like eczema
- Talk to close contacts and family members about the vaccination program and safety precautions
- Ask for assistance at any point, if you or your Family members have safety concerns
- Screening form can be located at: www.smallpox.mil/screeningform

All potential vaccinees must be screened



CHRONOLOGICAL RECORD OF MEDICAL CARE

Smallpox Vaccination Initial Note Page 1 of 2

This page may be completed by potential vaccine recipient

Shade Circles Like This--> ●
Not Like This--> ⊘ ✓

1. Today's Date (MM/DD/YYYY) ☐☐/☐☐/☐☐☐☐

2a. GENDER ○ Male ○ Female 2b. First day of last normal menstrual period: ___/___/___

2c. FEMALES: Was your last menstrual period normal and on time? ○ Yes ○ No ○ Unsure

2d. Are you currently breastfeeding? ○ Yes ○ No

3. Could someone you LIVE WITH or YOU be pregnant? ○ Yes ○ No ○ Unsure

4. Did you ever receive smallpox vaccine? ○ Yes ○ No ○ Unsure

4a. IF YES: Were you vaccinated within the last 10 years? ○ Yes ○ No ○ Unsure

4b. IF UNSURE: Birth Year ☐☐☐☐ First Year in Military (if applicable) ☐☐☐☐

5. Have you ever had a serious problem after smallpox or other vaccination? (Describe below) ○ Yes ○ No ○ Unsure

6. Do you currently have an illness with fever? ○ Yes ○ No ○ Unsure

7. Are you allergic to any of these products: polymyxin B, neomycin, latex? ○ Yes ○ No ○ Unsure

Before vaccinating against smallpox, we want to know if you or your household close contacts have any of several medical conditions.

Please answer the following questions to the best of your knowledge.

	Myself	Close Contact
8. Do you OR someone you currently live with NOW HAVE any of the following skin problems: Psoriasis (scaly skin rash), Burns (other than mild sunburn), Impetigo (skin infection), Uncontrolled Acne, Shingles (herpes zoster), Chickenpox, Darier's disease or Other skin conditions (describe below)?	○ Yes ○ No ○ Unsure	○ Yes ○ No ○ Unsure
9. Do you OR someone you currently live with NOW HAVE or RECENTLY HAD a problem or take(s) medication that affects the immune system? For example: have or take medication for HIV, AIDS, leukemia, lymphoma, or chronic liver problem; have or take medication for Crohn's disease, lupus, arthritis, or other immune disease; have had radiation or X-ray treatment (not routine X-rays) within the last 3 months; have EVER had a bone-marrow or organ transplant (or take medication for that); or have another problem that requires steroids, prednisone or a cancer drug for treatment.	○ Yes ○ No ○ Unsure	○ Yes ○ No ○ Unsure
10. Have you OR someone you currently live with EVER HAD Eczema or Atopic Dermatitis? (Usually this skin condition involves an itchy, red, scaly rash that lasts more than 2 weeks. It often comes and goes.) IF YES or UNSURE: for either you or your close contact, Answer 10a-10e	○ Yes ○ No ○ Unsure	○ Yes ○ No ○ Unsure
10a. A doctor has made the diagnosis of eczema or atopic dermatitis.	○ Yes ○ No ○ Unsure	○ Yes ○ No ○ Unsure
10b. There have been itchy rashes that have lasted more than 2 weeks.	○ Yes ○ No ○ Unsure	○ Yes ○ No ○ Unsure
10c. At least once, there is a history of an itchy rash in the folds of the arms or legs.	○ Yes ○ No ○ Unsure	○ Yes ○ No ○ Unsure
10d. There is a history of eczema and food allergy during childhood.	○ Yes ○ No ○ Unsure	○ Yes ○ No ○ Unsure
10e. A doctor has made the diagnosis of asthma or hayfever (including first-degree relatives).	○ Yes ○ No ○ Unsure	○ Yes ○ No ○ Unsure
11. Are you being treated with steroid eye drops or ointment or have you had recent eye surgery?	○ Yes	○ No ○ Unsure
12. Do you have a heart or vessel condition, such as angina, earlier heart attack, coronary artery disease, congestive heart failure, cardiomyopathy, stroke, "mini stroke", chest pain or trouble breathing on exertion?	○ Yes	○ No ○ Unsure

13. Check EACH of the following conditions that apply to you: ○ Heart Condition before age 50 in mother, father, brother, sister ○ Smoke cigarettes now ○ High blood pressure ○ High cholesterol ○ Diabetes or high blood sugar

14. Do you have a child in home less one year of age? ○ Yes ○ No

15. Do you have other questions or have other concerns you would like to discuss? ○ Yes ○ No

Explain "other," "unsure," or additional concerns (may use additional page). NOTE: If you might have a risk factor for HIV infection, we can arrange for HIV testing. FOR FEMALES: If you might be pregnant, or likely to become pregnant, please tell us. You may need additional pregnancy testing.

Last Name

First Name MI

Social Security Number

Patient's identification (May use mechanical imprint)

RECORDS MAINTAINED AT:
RANK/GRADE
SEX
DATE OF BIRTH
SPONSOR NAME
(or Sponsor SSN)
RELATIONSHIP TO SPONSOR
(Or FMP)
ORGANIZATION
STATUS
DEPT/SVC

Standard Form 600 (Rev.8-97) Electronic Copy SVP Overprint (2-08)

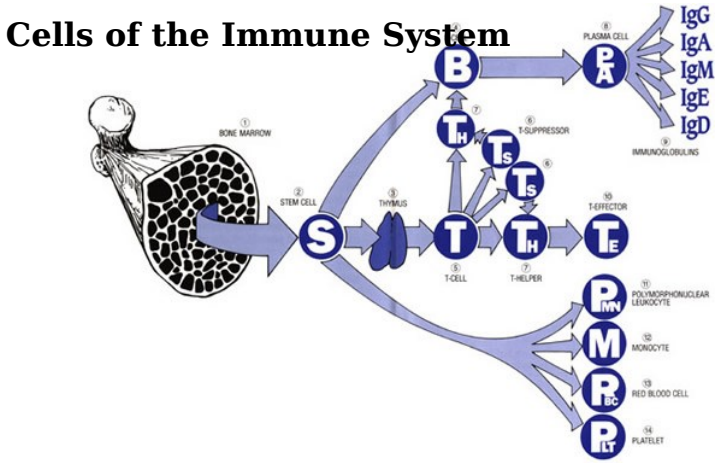
Exemptions to Vaccination

Some people should not get smallpox vaccine except in emergency situations.

Medical Exemptions are given for:

Personal <u>or</u> household contraindication

- Immune system is not working fully (due to disease, medication, or radiation)
- Has or has ever had eczema or atopic dermatitis
  - Red itchy, scaling rash lasting more than 2 weeks, comes & goes
- Has active skin diseases, such as:
  - Burns, psoriasis, contact dermatitis, chickenpox, shingles, impetigo, uncontrolled acne, until it clears up or is under control
- Pregnancy



Personal contraindication only

- Has a serious heart disease (such as angina, heart attack, congestive heart failure, other cardiac problem) or $\geq$ 3 risk factors
- Uses steroid eye drops or ointment or is recovering from eye surgery (1st 8 weeks post-op)
- Breast-feeding (avoid vaccination in families w/ infant < 1 yr old unless separated)
- Is allergic to a vaccine component such as polymyxin B, or neomycin

Screening for HIV

- HIV infection is a contraindication to smallpox vaccination
- Service members must be up-to-date with Service HIV screening policies before smallpox vaccination
- Civilian personnel will be offered an HIV test before vaccination.
- HIV testing recommended for anyone with a history of risk factors for HIV infection, especially since last HIV test, and not sure of HIV infection status
- Because known risk factors cannot be identified for some people infected with HIV, people concerned they could be infected should be tested

Contact Contraindications

People who have close contact with a person who has a contraindication to smallpox vaccination shall:

- Have alternative housing arrangements or be exempted from smallpox vaccination until household contact situation no longer applies (i.e., 30 days after vaccination)

Unacceptable:

- Permitting vaccinated SM to reside in house, trailer, apartment, or similar close arrangements (e.g., “hot-bunking”) with medically-barred contact

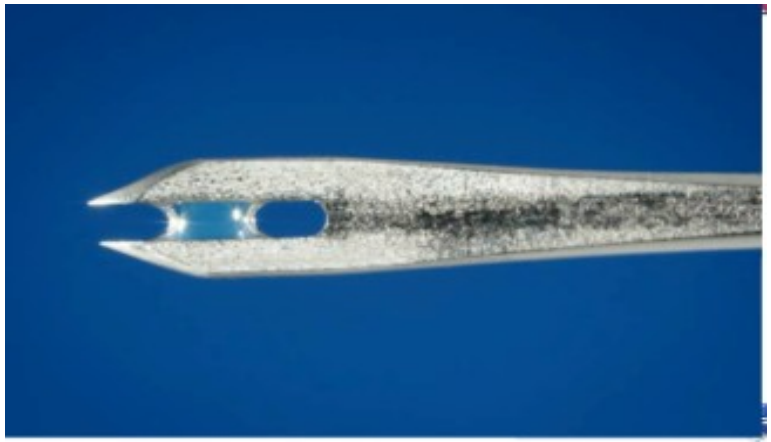
Acceptable:

- Vaccinated SM uses alternate lodging (e.g., barracks, dorm room, tents) on military installation, vessel, or aircraft, or in contracted space
- Berthing barges, familiar to naval forces in shipyards
- Vaccinated SM voluntarily arranges for alternate lodging in privately-owned or managed space is acceptable, if the commander has reasonable expectation that SM will comply with requirement
- Schedule vaccinations shortly before or during 2- to 4-week deployments or family separation

Timing with Other Vaccines

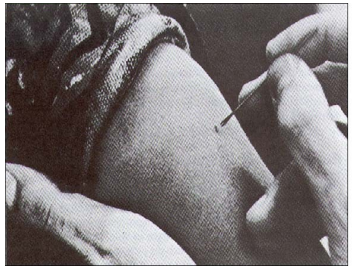
- **Advisory Committee on Immunization Practices (ACIP)** accepts administration of live and inactivated vaccines simultaneously or at any interval.
- Multiple live-virus vaccines should be given simultaneously or separated by 28 days or more
- To avoid confusing potential side effects, separate varicella (chickenpox) and vaccinia (smallpox) vaccinations by 28 days
- Purified Protein Derivative (PPD) can be given simultaneously or 4 weeks after SPV
- Do not administer other vaccines near smallpox site

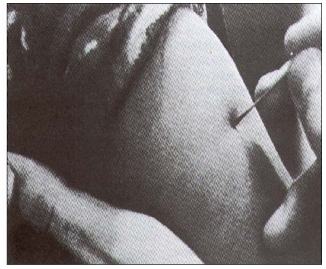
Bifurcated needle

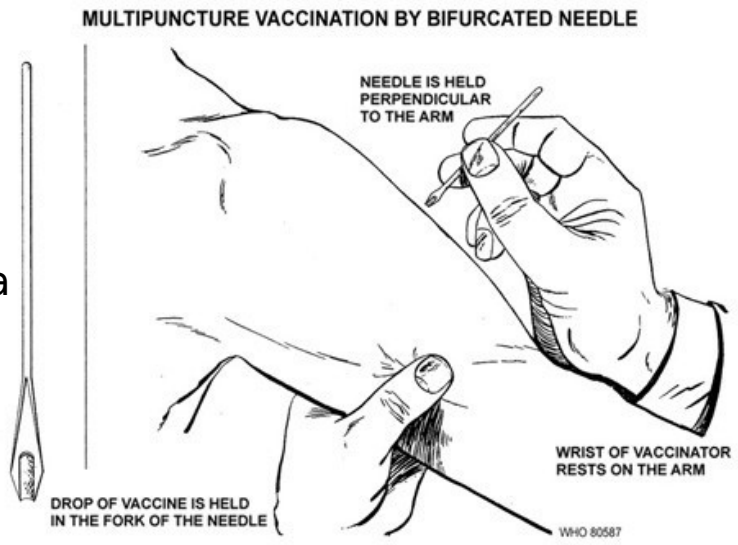


Vaccination Technique

- Vaccinators must have documented smallpox training in accordance with service requirements and must have previous smallpox vaccination and no current contraindications to the vaccine. Civilian vaccination is highly recommended prior to handling or administering smallpox vaccine.
- Site: Skin over deltoid or posterior arm over triceps
  - Do not vaccinate over an old smallpox site, tattoo, scar or open skin.
- Cleanse site with soap & water, then dry (if dirty)
- Use acetone or alcohol only if adequate time is allowed for site to dry (or wipe site dry with gauze to prevent inactivation)
- Multiple-puncture technique uses bifurcated needle inserted vertically into the vaccine vial
- Primary (first) vaccination: 15 punctures, rapidly in 5 mm area, with strokes vigorous enough to cause a trace of blood after 15-20 seconds
- Revaccination: 15 punctures
- Evidence of prior smallpox vaccination (rough descending order of reliability):
  - medical documentation
  - characteristic Jennerian scar
  - entry into U.S. military service before 1984
  - birth in the United States before 1970






MULTIPUNCTURE VACCINATION BY BIFURCATED NEEDLE
NEEDLE IS HELD PERPENDICULAR TO THE ARM
WRIST OF VACCINATOR RESTS ON THE ARM
DROP OF VACCINE IS HELD IN THE FORK OF THE NEEDLE
WHO 80587

Successful Response to Vaccination

DAY 4

DAY 7

DAY 14

DAY 21

If someone does not get the expected vaccination site reaction, the original vaccination clinic should be informed

Revaccination

- **Revaccination**
  - No take: Give one revaccination with 15 punctures (jabs)
  - If a vaccinee does not respond to a second attempt at vaccination, refer for immunologic evaluation
- **Pre-event**
  - Revaccinate if > 10 y elapsed since last vaccination
- **Outbreak**
  - Revaccinate if > 3 y elapsed since first vaccination

Documentation

- Screening: Record contraindications in medical record and ITS
- Vaccination: Individual medical records and ITS
- Confirmation of Take
  - Instruct all to come back to clinic if no characteristic lesion
  - Healthcare workers and response team members (traveling into smallpox outbreak area) will have take recorded in their health records and ITS
  - Other personnel should have vaccination take recorded in health records and ITS by medic or provider trained in vaccination evaluation
- Adverse events
  - Medical records, VAERS, VHC access
- USD(P&R): Services will audit immunization tracking systems

Care of Vaccination Site

Vaccine virus remains at the site for at least 30 days and until the skin has healed, and can potentially infect others

Instruct your patients of the following :

- **Don't touch any vaccination site**
- **If you touch it by accident, wash your hands right away**
- **Don't let others touch your vaccination site or materials that covered it**
- **Don't let others use a towel used after vaccination until laundered**
- **Wear sleeves to cover the site**
- **Wear sleeves at night, if you sleep in bed with someone**
- **Use bandages; change them every few days**
- **Discard bandages in sealed or double plastic bags; carefully add bleach if desired**
- **Keep site dry; bathe normally, but dry the site last, with something disposable (avoid rubbing)**
- **Avoid swimming or public bathing facilities**
- **Launder clothing, towels and sheets in hot water with detergent or bleach**
- **When the scab falls off, throw it away in a sealed plastic bag and wash hands afterwards**

Hand Washing & Hand Hygiene

Wash hands with soap and warm water

- Rub hands together vigorously for at least 10 seconds
- Cover all surfaces of the hands and fingers
- Rinse hands with warm water
- Dry hands thoroughly with a paper towel
- Use paper towel to turn off the faucet

Alcohol-based waterless hand rinse, *e.g.*, CalStat®

- Excellent alternative if hands are not visibly soiled
- Apply product to palm and rub hands together, covering all surfaces of hands and fingers, until hands are dry
- May have sticky feel after repeated use – wash hands with soap and water as needed

Be extremely careful with contact lens use!

- Wearing glasses until the site heals is preferred
- If contact lenses are used, wash hands thoroughly before touching eyes or

Pregnancy & Infant Care

- Smallpox vaccination should be deferred until after pregnancy
- Avoid pregnancy for 4 weeks after vaccination
- If a female is pregnant at the time of vaccination, or if a vaccinee becomes pregnant within 4 weeks after vaccination,
  - Contact Smallpox Vaccine in Pregnancy Registry:
    - 619.553.9255
    - NHRC-birthregistry@med.navy.mil
    - www.smallpox.mil/pregnancy
  - Submit VAERS with Smallpox Pregnancy Supplement
- In an outbreak, personal benefit from vaccination may outweigh risks
- Take care to prevent spread of vaccine virus to children. ALWAYS wash hands before handling (e.g., feeding, changing diapers) and keep site covered with a bandage and sleeves
- Smallpox vaccine not recommended for nursing mothers, as it may put infants in close contact with mother's vaccination site

Extra Precautions for Healthcare Workers

- Minimize contact with unvaccinated patients until 30 days after vaccination and until scab falls off
- If contact essential and unavoidable, workers can continue to work with patients, including those with immunodeficiencies:
  - If site well-covered and thorough hand-hygiene maintained
  - Semi-permeable bandage (Opsite, Tegaderm, Cosmopore)
- To prevent accumulation of exudates, cover site with dry gauze and apply dressing over gauze
- Change dressing daily (according to type of bandaging and amount of exudate), at the start or end of shift
- Site-care stations: to monitor worker vaccination sites, promote effective bandaging and encourage scrupulous hand hygiene
- Long-sleeve clothing further reduces risk for contact transfer
- Most critical measure: Thorough hand-hygiene after changing bandage or any contact with site

Symptoms Reported After Vaccination

Day 6-8, symptoms after vaccination, n = 5,951, Jan-Apr 2003

• Local itching	62%	Muscle ache	27%
• Feeling lousy	26%	Lymph nodes swell	23%
• Headache	23%	Bandage reaction	16%
• Itchy all over	11%	Fever (subjective)	6.6%
• Local rash	11%	Body rash	2.3%

• Restrict activity	2.4%	Took medication	5.0%
• Outpatient visit	1.1%	Limited duty	0.3%
• Missed work	0.4%	Hospitalized	0.1%

www.smallpox.mil/safety

Serious Adverse Events

Serious reactions that may require medical attention

- Accidental spread of virus elsewhere on body or to another person
- Widespread vaccine rash where sores break out away from vaccination site (generalized vaccinia)
- Allergic rash after vaccination (erythema multiforme)
- Inflammation of or around heart (myo-pericarditis)

Life-threatening reactions that need immediate attention

- Serious skin rashes in people such as those with eczema or atopic dermatitis (eczema vaccinatum)
- Ongoing infection of skin with tissue destruction (progressive vaccinia or vaccinia necrosum)
- Postvaccinal encephalitis, inflammation of the brain
- Chest pain or shortness of breath

Treatment of Adverse Events

- Be alert for serious, rare adverse events after vaccination
- Consult the Vaccine Healthcare Centers Network or other specialists as appropriate (allergy-immunology, infectious disease, dermatology, neurology, cardiology, etc.)
- Some conditions respond to vaccinia immune globulin (IV-VIG)
  - Eczema vaccinatum, progressive vaccinia, severe ocular vaccinia, severe generalized vaccinia
  - IV-VIG not effective in treating post-vaccinial encephalitis
- IV-VIG consists of human IgG antibody from people vaccinated with smallpox vaccine
- Contact the CDC Director's Emergency Operation Center (DEOC) to order IV-VIG at (770) 488-7100

Adverse Event Reporting

- Vaccine Adverse Event Reporting System (VAERS)
  - FDA and CDC review 100% of reports submitted
  - Anyone can submit a VAERS form, online preferred https://secure.vaers.org
  - Reporting with medical help results in more detail
- DoD requires a VAERS form for:
  - Loss of duty 24 hours or longer (≥ 1 duty day)
  - Hospitalization
  - Suspected vaccine vial contamination
  - Auto-inoculation or contact vaccinia
- Other submissions encouraged
- Report to VAERS at www.vaers.hhs.gov or call 800-822-7967
- For assistance with VAERS submission contact your local clinic or the VHC Network

AskVHC@amedd.army.mil or www.VHCInfo.org

Reserve Adverse-Event Care

- Adverse events after DoD or USCG directed vaccinations are line-of-duty conditions
- Someone with an adverse event in a non-duty status possibly associated to any vaccination
  - Seek medical evaluation at a DoD, USCG, or civilian medical treatment facility, if necessary
  - Must report the event to the unit commander or designated representative as soon as possible
  - See local medical department or squadron for guidance
- Commander will determine Line of Duty and/or Notice of Eligibility status, if required

Information Sources

MILVAX Agency

- www.smallpox.mil; www.vaccines.mil/smallpox
- vaccines@amedd.army.mil
- 877.GET.VACC (877.438.8222)

DoD Vaccine Clinical Call Center

- 866.210.6469

DoD Vaccine Healthcare Centers

for help with complicated adverse-event management

- www.vhcinfo.org
- Askvhc@amedd.army.mil
- 202.782.0411

Information for Civilian Healthcare Providers

Call the Military Treatment Facility (MTF) where the member is enrolled

–OR– contact the Military Medical Support Office (MMSO)

- 888.647.6676 *(if the member is not enrolled to an MTF)*

Smallpox Vaccine in Pregnancy Registry

- NHRC-birthregistry@med.navy.mil
- 619.553.9255

MILVAX

www.vaccines.mil